EXHIBIT J

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., **PELVIC REPAIR SYSTEM PRODUCTS** **LIABILITY LITIGATION**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: ***Patricia Conti v Ethicon, Inc., et al*** ***Case No. 2:12-cv-00516***	

Case Specific Expert Report of Marc R. Toglia, M.D.
Patricia Conti case

I. Qualifications

I am a sub-specialist in the field of Female Pelvic Medicine and Reconstructive Pelvic Surgery. I am double board certified in Female Pelvic Medicine and Reconstructive Surgery (2012) and Obstetrics and Gynecology (1995) and am licensed to practice medicine in Pennsylvania. Currently I serve as the Chief of Female Pelvic Medicine and Reconstructive Surgery for the Main Line Health System in suburban Philadelphia. I also hold the academic title of Associate Professor of Obstetrics and Gynecology at Thomas Jefferson School of Medicine and Associate Clinical Professor at the Lankenau Institute of Medical Research (LIMR). For additional information regarding my qualifications, training and experience, please refer to my attached Curriculum Vitae (Exhibit A) and my General Expert Report on the TVT which I incorporate in this case specific report.

II. Materials Reviewed

In preparation of my opinions I have reviewed the medical records and depositions in this case. I have searched and reviewed the medical and scientific literature through Medline and Cochrane databases and bibliography searches of studies. I have also incorporated my personal surgical experience over the past 24 years and information gathered at national and international scientific meetings that I attended during this time period. I have also reviewed the pertinent Ethicon Instructions for Use, Monographs, Professional Education materials, and other Ethicon documents. I have also reviewed the reports and materials cited by Plaintiff's experts. A list of these materials and those that I may use at trial are attached to this report as Exhibit B.

III. Fees and Expert Testimony

My fees for serving as an expert in this matter are: $400/hour for review, report drafting and meetings and $4,000/day for deposition and trial testimony. I have given expert deposition testimony in the prior four years in the Mullins v. Ethicon TVT case on October 2, 2015.

IV. Brief Case Summary

Patricia Conti presented to Dr Gregory Bolton, Jr as a 49yo female with complaints of urinary leakage, nocturia, frequency and urgency on 11/17/05. She had previously undergone hysterectomy at age 29, and also had a previous appendectomy and had a history of endometriosis. According to paperwork completed by the patient, she had been experiencing incontinence for 3-4 years, and this was occurring more than once a day. She reported urinary frequency, voiding every hour, nocturia 3-7 times a night, with urgency present 50% of the time. Her symptoms had worsened over the past 6-12 months, and leakage was occurring night and day. She described leakage with cough, sneeze and exercise, as well as on the way to the bathroom. She was using 2-3 liners a day, and reported having to change her clothes occasionally because of leakage.

Ms Conti underwent a TVT sling by Dr Bolton on 12/21/05. There were no reported complications. A postop visit on 12/21/05 indicated that she was doing well, with no SUI, with a plan to start Detrol LA for persistent Overactive bladder symptoms and to continue with pelvic physical therapy.

On November 17, 2006, Ms. Conti presents to Dr James Booker, a urologist in Winter Haven , Florida with complaints of urinary incontinence. Dr Booker notes vaginal mesh exposure and recommends cystoscopy, which is performed on 11/30/06. He notes that the bladder mucosa appeared normal, and that no sling was noted through the mucosa, however, there was one area on the right side of the bladder dome where the sling appeared to be just submucosal. She next sees Dr Lotenfoe, another urologist, who orders a CT scan of the pelvis with contrast, and this study was reported as negative. Dr Lotenfoe also performs urodynamic studies which reports stress incontinence and detrusor overactivity. Ms Conti subsequently sees Dr Kathy Jones, a urogynecologist in Orlando, who also notes a 1 cm area of vaginal mesh exposure. Dr Jones also documented significant overactive bladder symptoms including urinary frequency, 20 times a day and nocturia,

Ms. Conti returned to see Dr. Bolton in 2007. He excised 2 cm of exposed vaginal mesh on 2/6/07. There was no mention of granulation tissue, inflammation, roping or curling of the mesh. On November 7, 2007, Ms. Conti underwent a cystoscopy under anesthesia which showed no evidence of erosion into the bladder mucosa. A vaginal exam showed no mesh in the vaginal canal.

Ms. Conti next sees Dr Miles Murphy, a urogynecologist at Abington Hospital, two year later, on July 17, 2009. The previous month, Ms Conti completed a series of quality of life questionnaires in preparation for this visit, including the UDI-6, POPDI-6 and PFIQ. Her answers reflect significant impact of her overactive bladder symptoms. Her responses to the Pelvic Floor Impact Questionnaire were notable in that she reported no impact of vaginal or pelvic symptoms on her social and emotional health or physical activities, but significant impact of her bladder symptoms on these domains. Her presenting complaints at the time were pelvic pressure, pain and vaginal discharge. Dr Murphy's evaluation including a provocative cough stress test which was negative for continence, and a uroflowmetry study which revealed a voided volume of 261 ml and a post void residual of zero. His pelvic exam revealed "diffuse tenderness", but he was unable to visualize or palpate any exposed mesh, and noted no areas of specific inflammation and did not see any abnormal vaginal discharge. Dr Murphy offers her continued expectant management and conservative treatment, however, Ms. Conti is insistent on surgical removal of the sling despite Dr Murphy's warning of multiple potential problems including incontinence and more severe pelvic pain.

On July 17, 2009, Dr. Murphy met with Ms. Conti regarding her desire to have the mesh removed. Ms. Conti was reportedly experiencing frequent urination, urge incontinence, and stress urinary incontinence. Her symptoms were moderately affecting her physical activities. Dr. Murphy testified that return of incontinence is a risk in any sling revision. He further stated that a patient can have pain because of surgery itself and not necessarily from the implant.

Dr Murphy subsequently removes portions of the sling on 11/17/09. He removed two long strips of sling mesh through a "short Pfannenstiel incision". He reports no complications and minimal blood loss. Of significance, the pathology report states no inflammatory features. There was no mention of any inflammation, curling, or roping of the mesh in either the operative report or pathology report.

Dr Murphy next performs urodynamic studies on 8/18/10. The patient presented for the study with a bladder volume of 727 ml, and voided 683 ml during a spontaneous uroflow. Her cystomatric capacity during filling cystometry was 454 ml, and during filling detrusor contractions were demonstrated. Stress incontinence was demonstrated as well.

Ms Conti next presents to Dr Brett Lebed, a urologist in Montgomery County, PA, an symptoms of mixed incontinence were recorded. He documents urinary frequency, every 10 -30 minutes with urinary urgency greater than 80% of her

voiding, nocturia 4-5 times, multiple episodes of urge incontinence as well as stress incontinence. Video urodynamics were performed by Dr Lebed, who reports these findings on 2/23/11, consistent with detrusor overactivity incontinence at small volumes. Although he notes stress incontinence on provocative testing, he also notes stress induced involuntary bladder contraction with leak. In a letter to Dr. James Nicholson, Dr Lebed communicates that he offered Ms. Conti further testing in the form of peripheral neuromodulation and Botox to treat her small bladder capacity, stress induced detrusor overactivity and urge incontinence, but she was unwilling to proceed with these recommendations. Instead, Ms. Conti chose to proceed with an autologous fascial sling, despite a discussion suggesting that a third of patients would experience worsening urinary urgency after such an intervention

Dr Lebed performed an autologous rectus fascia sling on 3/28/11 to improve her stress incontinence. While her urinary symptoms initially improved, she presented with worsening urinary symptoms, including urgency and urge leakage within five months, as well as difficulty getting her urinary stream started. She subsequently underwent two revisions of the sling by Dr Lebed. At the time of her last visit with Dr Lebed, that was available for my review, on 7/10/12 Ms. Conti complained of very rare stress incontinence, occasional urgency and urge incontinence. In September 2011 , she had a small piece of the stitches excised.

V. Independent Medical Evaluation

Ms. Conti was evaluated in my office in Media, PA on 2/25/16. She is presently 59 years old. She was polite and cooperative throughout the evaluation. She recalls her TVT procedure with Dr. Bolton in 2005, for what she describes as mostly stress leakage. She recalls that the procedure was uncomplicated and that she had an easy recovery, and did experience significant improvement in her stress leakage. She does not recall having significant pain peri-operatively. She states that the following year, she spent a significant amount of time in Florida. In June of that year, she began to have some pinching pain described as a prickly feeling in the vagina and some light spotting. This prompted her visit to Dr. Booker later that year. At the time of her presentation to Dr Murphy, she recalls experiencing some vague suprapubic pressure. She was sexually active at the time, and reports some deep seated pain with intercourse, but no pain with vaginal penetration near the opening of the vagina. She also recalls that the recovery from the autologous fascial sling was significantly more difficult than the TVT sling.

At the present time, Ms. Conti states that she has some leakage of urine with activity such as cough or sneeze approximately three times a week. She denies wearing a pad or the need to change clothes because of leakage. She does not get up at night to go to the bathroom, and feels that her bladder empties well. She has some urinary urgency at times, and occasional urgency leakage. She is not sexually active at present, and denies any vaginal bleeding. She stated that she does get urinary tract infections frequently. She has a deep burning sensation internally, mostly under her Pfannenstiel incision. On exam, Ms. Conti is well developed and not in any distress. Her abdominal exam is unremarkable, and her Pfannestiel incision is well healed without evidence of a hernia. There is some discomfort elicited with deep pressure on the incision. On vaginal exam, the external genitalis appear normal but atrophic. There is no introital stenosis, and the vagina fits two fingers snugly at the introitus. The urethra is supported, there is no evidence of stress leakage with coughing. There is no exposed or palpable mesh under the urethra. There was no periurethral tenderness appreciated and the obturator internus and levator ani muscles were non tender to touch. The vagina showed moderate atrophy but there was no discharge or bleeding. The uterus and cervix were surgically absent. The vagina is well supported.

VI. Opinions

What follows are my opinions and the bases for the opinions. They are based on my education, training, professional experience, clinical research and teaching I have performed, my review of the medical records, depositions and other case specific materials, the medical and scientific literature, as well as my experience as an editor for the leading medical journals in my field. This report is based on the records and information currently available and if I receive additional information between now and the time of the trial, I may form additional opinions or some of my opinions may be modified. All of my opinions are held to a reasonable degree of medical certainty. I incorporate my general TVT report fully herein.

In 2005, the retropubic TVT was established as the gold standard first line therapy for the management of SUI. It is an appropriate choice in managing women with mixed incontinence that have significant stress urinary incontinence. The records suggest that her SUI symptoms are significantly improved after the procedure. However, she also had pre-existing overactive bladder symptoms that continued to worsen over time. This problem is independent of her stress incontinence, and not related to her TVT sling specifically. Ms. Conti has had nearly all of the TVT sling removed at this point. Her current complaints of difficulty voiding and urgency leakage are more likely the result of her subsequent treatments with Dr. Lebed,

namely, the autologous sling and the surgical revisions that followed. It is important to note that Ms. Conti continued to have chronic urinary complaints despite the autologous sling, which would have hypothetically been an alternative to the initial TVT sling. This highlights the fact that complications such as voiding dysfunction and urge incontinence as well as recurrence are common to all anti-incontinence procedures

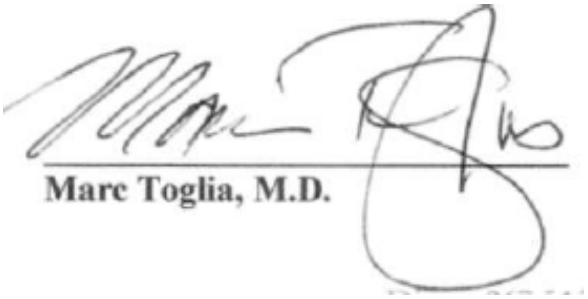
Ms. Conti has had ongoing complaints of vaginal discharge, but this finding was not confirmed by any of her examining physicians, notably Drs Bolton, Jones or Murphy. It was also not present during my examination.

It is difficult to assign a cause for her complaints of vaginal and pelvic pain, but in my opinion, it is not the result of her TVT sling, which at this point, has been completely removed. On my examination, Ms. Conti refers to her lower abdominal incision as the site of her discomfort. It should be noted that this incision has been opened multiple times – initially for her hysterectomy, and subsequently by Dr. Murphy (at the time of the TVT removal), Dr Lebed – it is the site where the autologous sling was harvested. According to the medical records, complaints of vaginal and pelvic pain are not listed by her treating physicians subsequent to the revision performed by Dr. Murphy. Specifically, the records of Dr Brett Lebed do not reflect pain amongst the chief complaint or HPI in any office notes from 2/9/11 to 7/10/12. Ms. Conti has multiple risks and pre-disposing factors for chronic pain, including her hysterectomy that was performed at age 29 for endometriosis and pain, and she is currently on disability for chronic neck pain, having undergone surgeries for this condition in 2007, 2013, and 2015. During my evaluation of Ms. Conti, she reported that her hysterectomy was performed for severe menstrual pain, and recall that her surgeon stated that he did not find much abnormal at the time of that procedure. There is no evidence of nerve pain or muscle spasm. It is my opinion that Ms. Conti's current complaints of pelvic burning are unrelated to her prior TVT sling.

At the present time, Ms. Conti has no complaints of urinary retention or difficulty voiding. Throughout her medical records, there is evidence that she suffered with progressive urgency incontinence, which preceded her TVT procedure. She had evidence of detrusor overactivity on Urodynamic testing on several occasions, and it would appear that her symptoms worsened over time, and that Dr. Lebed had suggested third line therapy to treat this at his initial evaluation. It is my opinion, to a reasonable degree of medical certainty, that these symptoms are unrelated to her TVT sling. Of note, Ms. Conti has far less complaints of urgency and urge leakage at the present time. The recurrence of her SUI can be explained by the

removal of her TVT sling, and subsequent two revisions of her autologous fascial sling.

There is no evidence that Ms. Conti has introital stenosis, and I would agree with Dr Lebed's statement from his deposition that most likely reflected vaginal atrophy. There is no reason to believe that a suburethral, retropubic sling would result in introital stenosis.



Marc Toglia, M.D.

Date: February 28, 2016